In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 15-1553V
Filed: December 3, 2021
UNPUBLISHED

JONATHAN PATTON, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Remand; Ruling on Entitlement; Influenza Vaccination; Brachial Neuritis

Michael Andrew London, Douglas & London, P.C., New York, NY, for petitioner.
Claudia Barnes Gangi, U.S. Department of Justice, Washington, D.C., for respondent.

Ruling on Entitlement[1]

On December 21, 2015, petitioner Jonathan Patton[2] filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[3] alleging that he suffered brachial neuritis[4] as a result of his January 11, 2013 influenza vaccination. (ECF No. 1.) He later amended his claim to allege that he also experienced radiculomyelitis as a result of the same vaccination. (ECF No. 34.) Initially, I found petitioner was not entitled to compensation (ECF No. 83); however, the Court of Federal Claims granted petitioner's motion for review of that decision and remanded the case for

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] In fact, when the petition was filed, Mr. Patton was a minor and the action was brought by his mother on his behalf. Petitioner was subsequently substituted as petitioner on February 18, 2016. (ECF No. 10.)

[3] All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

[4] Throughout the record of this case, three terms – i.e. brachial neuritis, Parsonage-Turner syndrome, and neuralgic amyotrophy – have been variously used to describe the same basic condition. Notwithstanding any nuances, the parties and experts have treated the terms as interchangeable.

further proceedings (ECF No. 91). On remand I find that petitioner is entitled to compensation for brachial neuritis caused-in-fact by his influenza vaccination for all the reasons discussed below.

I. Factual and Procedural History[5]

a. Factual history, briefly

Apart from a history of nosebleeds, petitioner was a healthy 15-year-old boy prior to receiving a flu vaccine on January 11, 2013. (Ex. 2, p. 3.)[6] Petitioner received the typical childhood vaccines during his infancy and never experienced any neurological symptoms nor was he ever diagnosed with any neurological or autoimmune condition. (Ex. 1, pp. 1-2; ECF No. 72, p. 1.) Petitioner's pertinent medical history begins on January 11, 2013, when he received the flu vaccine that serves as the basis for this claim.

On January 17, 2013, six days after receiving the flu vaccine, petitioner awoke early in the morning with a nosebleed that was more severe than usual. (Ex. 2, p. 2.) Petitioner was unable to move his arms, describing the feeling as "dead weight." (*Id.*) After alerting his mother of his condition, petitioner was brought and admitted to the All Children's Hospital ("ACH") Emergency Department. (*Id.*) Petitioner's arms were so weak at this point that he was unable to dress himself or fasten his seatbelt on his own. (Ex. 7, p. 59.) He also reported he had experienced an occipital headache, neck pain, and bilateral shoulder pain since waking. (*Id.*)

Petitioner's initial presentation seemed to confuse his treating physicians at ACH who initially listed 13 differential diagnoses including central nervous system mass, carbon monoxide poisoning, dehydration, electrolyte abnormality, unspecified headache, migraine, tension headache, intracranial hemorrhage, meningitis, post-concussion syndrome, shunt malfunction, and stroke. (Ex. 7, p. 60.) However, as petitioner was further examined, his treating physicians and physical therapists settled on a diagnosis of possible or probable brachial neuritis (referenced as Parsonage-Turner syndrome) that they related to his flu vaccination. (Ex. 7, pp. 17, 47, 85.)

b. Initial decision denying entitlement to compensation

As noted above, petitioner's claim was filed on December 21, 2015, alleging that Mr. Patton suffered brachial neuritis caused by his flu vaccination. (ECF No 1.) However, during the pendency of the claim petitioner also alternatively alleged he

[5] The facts and procedural history are described in greater detail in the now vacated May 17, 2021 Decision dismissing this case (ECF No. 83 (vacated); *see also Patton v. Sec'y of Health & Human Servs.*, No. 15-1553V, 2021 WL 2389835 (Fed. Cl. Spec. Mstr. May 17, 2021)) as well as in the Court's Opinion and Order granting petitioner's motion for review (ECF No. 91; *see also Patton v. Sec'y of Health & Human Servs*., No. 15-1553V, 2021 WL 5445549 (Nov. 22, 2021).)

[6] Exhibit 2 was not bates-stamped. This decision cites to the pagination generated by CM/ECF.

suffered radiculomyelitis. (ECF No. 34.) Petitioner initially filed a supporting expert opinion by neurologist Thomas Morgan, M.D., who opined petitioner suffered radiculomyelitis, but not brachial neuritis. (Exs. 12, 17.) Dr. Morgan later became unavailable to continue the case and petitioner then relied on an opinion by neurologist Salvatore Napoli, M.D., who agreed that petitioner suffered radiculomyelitis, but also opined that petitioner suffered brachial neuritis as originally pled. (Ex. 21.) Respondent offered a competing opinion by neurologist Vinay Chaudhry, M.D., who opined petitioner's condition was not consistent with either condition and, in fact, defied diagnosis. (Exs. A, G, H.)

Neither radiculomyelitis nor brachial neuritis constitutes a Table Injury[7] relative to the flu vaccine at issue in this case. (Brachial neuritis is a Table Injury relative to tetanus-containing vaccinations only.) Accordingly, petitioner is obligated to prove by preponderant evidence that his flu vaccination "caused-in-fact" his injury. *See* 42 C.F.R. § 100.3(a); § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). To meet this burden, petitioners must generally satisfy what has come to be known as the three-part *Althen* test, which requires: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

An entitlement hearing was held on October 27, 2020. (*See* ECF No. 80, Transcript of Proceedings ("Tr"), October 27, 2020). Thereafter, I issued a decision denying entitlement to compensation on May 17, 2021. (ECF No. 83 (vacated).) That decision sought to resolve three overarching questions: whether there is preponderant evidence petitioner suffered radiculomyelitis; whether there is preponderant evidence petitioner suffered brachial neuritis; and whether there is preponderant evidence petitioner's injury was caused-in-fact by his flu vaccination. (ECF No. 83, p. 20.)

First, as a threshold matter, I concluded that there was preponderant evidence supporting the diagnosis of brachial neuritis, which was the diagnosis reached by the treating physicians, but not preponderant evidence supporting the diagnosis of radiculomyelitis, which was proposed by petitioner's experts, but not considered by the treating physicians. (ECF No. 83, p. 23.) Having determined that petitioner substantiated only the brachial neuritis diagnosis, I conducted an analysis pursuant to the *Althen* test focused on that condition. (*Id.*)

I explained with respect to *Althen* prong one (petitioner's required medical theory), that Dr. Napoli theorized that brachial neuritis can be caused by the flu vaccine via the well-known concept of molecular mimicry. (ECF No. 83, p. 28 (citing Tr. 16, 38-

[7] In some cases, a petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, petitioners may show that they suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. In such cases, the Table Injury is presumed to have been caused by the vaccine. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

39; ECF No. 77, pp. 35-39).) In addition to citing case reports, his opinion was based largely on the ideas that brachial neuritis is understood to be an autoimmune condition generally and that the flu vaccine has separately, but more specifically, been shown to cause another peripheral nerve condition, Guillain Barre Syndrome ("GBS"), via molecular mimicry. (*Id*. at 29 (citing Tr. 94; Ex. 21, pp. 5-6; Ex. 26[8], p. 3; Ex. 23[9], p. 16).) However, I accepted respondent's expert's opinion which suggested that this was not a reliable theory because the evidence supporting vaccine causation of GBS only supports molecular mimicry between the flu vaccine and the myelin sheath of the nerve. The condition of brachial neuritis at issue in this case, by contrast, is generally understood to be a condition specifically affecting nerve axons rather than myelin. (*Id*. at 29 (citing Tr. 131-33, 279-80; Ex. C[10], p. 7; Medlink, *supra*, at Ex. 23, p. 2).)

Dr. Chaudhry testified that the myelin and axons are susceptible to different antigens and also filed literature showing that the understanding that brachial neuritis is an autoimmune condition is supported by studies demonstrating the nerve axons specifically to be the autoimmune target in that particular condition. (ECF No. 83, pp. 29-30 (citing Tr. 131-32; Van Eijk, Groothuis & Van Alfen, *supra*, at Ex C, p. 5).) I concluded that Dr. Napoli had not demonstrated that the flu vaccine can cause axonal loss lesions as seen in brachial neuritis as opposed to the type of demyelinating injury seen in GBS. Thus, I found that Dr. Napoli had not demonstrated that the flu vaccine *can cause* brachial neuritis and petitioner did not meet his burden of proof under *Althen* prong one with respect to the condition of brachial neuritis. (*Id*. at 31.)

With respect to *Althen* prong two, petitioner is obligated to come forward with evidence demonstrating a logical sequence of cause and effect showing that his vaccination *did cause* his own injury. Because the *Althen* analysis was predicated on petitioner's preponderant showing that his condition was diagnosed as brachial neuritis, my analysis pursuant to *Althen* prong two flowed directly from the analysis under *Althen* prong one.

In this case, petitioner's treating physicians had concluded both that petitioner's injury was brachial neuritis and that it was caused by his flu vaccine; however, the latter conclusion was supported only by temporal association and the lack of an alternative explanation. (ECF No. 83, p. 32 (citing Ex. 7, pp. 17, 47, 53, 85).) Accordingly, because I had concluded there is not preponderant evidence that the flu vaccine can cause brachial neuritis as a matter of general causation, I afforded their opinions as to specific causation only "little" weight. (*Id*. (citing *D'Angiolini v. Sec'y of Health & Human Servs.,* No. 99-578V, 2014 WL 1678145 (Fed. Cl. Spec. Mstr. Mar. 27, 2014) (noting that "there is a difference between a doctor's opinion regarding diagnosis and a doctor's opinion regarding etiology and quoting *Tamraz v. Lincoln Electric Co*, 620 F. 3d 664,

[8] Penina Haber et al., *Vaccines and Guillain-Barre Syndrome*, 32 DRUG SAFETY 309 (2009).

[9] Mark A Ferrante & Francesc Graus, *Neuralgic Amyotrophy*, NEUROLOGY MEDLINK (2020) (herein "Medlink").

[10] Jeroen van Eijk, Jan T. Groothuis & Nens van Alfen, *Neuralgic Amyotrophy: An Update on Diagnosis, Pathophysiology, and Treatment Muscle Nerve*, 53 MUSCLE AND NERVE 337 (2016).

674 (6th Cir. 2010) for the proposition that physicians "may testify to both [diagnosis and etiology] but the reliability of one does not guarantee the reliability of the other"), *mot. for rev. denied,* 122 Fed. Cl. 86 (2015), *aff'd*, 645 F. Appx 1002 (Mem.) (Fed. Cir. 2016).))

Although Dr. Napoli had opined that petitioner's condition could be explained as brachial neuritis, I explained that his causal opinion was also predicated on his identification of both radiculomyelitis and brachial neuritis as relevant demyelinating conditions. (ECF No. 83, p. 33 (citing Tr. 107).) However, as described above, record evidence was persuasive in showing brachial neuritis to be a condition of axonal loss lesions. (*Id*. (citing Tr. 131-33, 279-80; Van Eijk, Groothuis & Van Alfen, *supra*, at Ex C, p. 7).) With respect to petitioner's own medical history, Dr. Napoli had indicated he could not determine from the record evidence whether petitioner's own condition was axonal or demyelinating. (*Id*. (citing Tr. 107).)

Pursuant to *Althen* prong one, my analysis indicated that Dr. Napoli had only demonstrated that demyelination injuries, but not axonal nerve injuries, were potentially caused by the flu vaccine. (ECF No. 83, pp. 28-31.) Accordingly, to the extent Dr. Napoli relied on a brachial neuritis diagnosis to explain petitioner's condition, he was not persuasive under *Althen* prong two in suggesting a logical sequence of cause and effect demonstrating that petitioner's flu vaccination actually *did cause* what was likely (by virtue of the nature of the diagnosis being relied upon) an axonal, rather than (as Dr. Napoli had assumed) a demyelinating nerve injury. (*Id*. at 33.) More specifically, I indicated that "[p]etitioner has failed to show by preponderant evidence a logical sequence of cause and effect whereby the flu vaccine would have induced an autoimmune reaction that caused his axonal-loss lesion resulting in brachial neuritis." (*Id*.) Alternatively, the specific condition Dr. Napoli had shown to be vaccine-caused, GBS, did not fit petitioner's own clinical presentation and there likewise was not preponderant evidence supporting the presence of the demyelinating radiculomyelitis proposed by petitioner's experts. (ECF No. 83, p. 33.)

Based on all of the above, I concluded that "[a]lthough petitioner's condition does remain somewhat enigmatic, he has not articulated any basis for concluding that his flu vaccine could be responsible for a logical sequence of cause and effect leading to his constellation of symptoms." (ECF No. 83, p. 33.) Thus, I found that petitioner had not satisfied his burden of proof under *Althen* prong two. (*Id*.)

Althen prong three, requiring a medically appropriate temporal relationship between vaccination and injury, was not litigated by the parties. I found that *Althen* prong three was satisfied, but nonetheless explained that petitioner's failure to meet *Althen* prongs one and two was dispositive. Accordingly, I issued a decision dismissing the case. (ECF No. 83, pp. 33-34.)

c. Motion for review and Court of Federal Claims remand order

Petitioner subsequently filed a motion for review which was granted by the Court of Federal Claims on November 5, 2021. (ECF No. 91.) Petitioner did not challenge

the finding that he did not suffer radiculomyelitis, but did challenge the finding that his brachial neuritis was not vaccine caused. (*Id*. at 2, n. 3.) On review, the Court of Federal Claims accepted Dr. Napoli's opinion that the flu vaccine can cause brachial neuritis and remanded the case for further proceedings.

The Court concluded that I had erred by giving too little weight both to Dr. Napoli's description of molecular mimicry as a well-accepted immunological concept and to the case reports cited by Dr. Napoli to specifically support a connection between the flu vaccine and brachial neuritis. (ECF No. 91, pp. 6-8.) Additionally, with respect to Dr. Napoli's reliance on literature addressing the relationship between the flu vaccine and demyelinating GBS, the Court held that it was error to accept Dr. Chaudhry's opinion that brachial neuritis is a distinct, axonal, injury. (*Id*. at 9-10.) The Court reasoned that the distinction drawn by Dr. Chaudhry cannot be applied in this case, even with respect to whether the flu vaccine can cause brachial neuritis pursuant to *Althen* prong one, because there is not sufficient evidence on this record to determine whether petitioner's own nerve lesions were axonal or demyelinating. (*Id*. at 10.) Specifically, the Court stated:

> It also appears that the Special Master rejected Dr. Napoli's opinion that the flu vaccine can cause brachial neuritis because he adopted Respondent's expert Dr. Chaudhry's opinion "that cases of brachial neuritis overwhelmingly result in axonal damage and not demyelination" . . . The Special Master concluded that Dr. Napoli did not provide evidence that a vaccine causing one type of nerve damage (demyelination) via molecular mimicry should be assumed capable of causing the other (axonal). But this distinction that Dr. Chaudhry drew between demyelinating nerve damage versus axonal damage cannot be applied to Petitioner on this record. As the Special Master found, "there is no evidence on this record distinguishing whether petitioner's symptoms were caused by demyelination or axonal damage."

(ECF No. 91, pp. 9-10. (internal citations and footnote omitted).)

Consistent with Dr. Napoli's framing of his opinion, the Court cited approvingly to literature filed by petitioner associating the flu vaccine to demyelinating GBS combined with literature asserting that unspecified vaccines are among the recognized triggers for brachial neuritis as evidence that the flu vaccine can cause brachial neuritis. (*Id.* at 10-11.)

The Court held that:

> Petitioner demonstrated a sound and reliable medical theory that the flu vaccine can cause brachial neuritis via molecular mimicry. This theory is supported by the expert opinion of an experienced neurologist, four case reports, three medical articles, and the diagnoses of four treating physicians that the flu vaccine likely did cause Petitioner's brachial neuritis. By disregarding this evidence and noting the absence of studies supporting

> Petitioner's theory, the Special Master placed too high an evidentiary burden on Petitioner with respect to *Althen*'s prong one.

(*Id*. at 11.)

Noting that my *Althen* prong two analysis had been colored by my *Althen* prong one analysis, the Court remanded the case with the following instruction: "On remand, the Special Master shall reassess entitlement in particular whether Petitioner satisfied *Althen*'s prong two in light of this Court's finding that Petitioner met *Althen*'s prong one." (*Id.* at 12.)

II. Discussion

As discussed above, petitioner is obligated to prove by preponderant evidence that his flu vaccination "caused-in-fact" his injury. *See* 42 C.F.R. § 100.3(a); § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). To meet this burden, petitioner must demonstrate: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

I previously found that there is not preponderant evidence that petitioner suffered radiculomyelitis and that finding was not challenged on review. Although I did find that preponderant evidence supported petitioner's brachial neuritis diagnosis, I concluded that condition was not vaccine caused owing largely to my analysis of general causation under *Althen* prong one. On review, the Court of Federal Claims held that petitioner satisfied *Althen* prong one specifically with respect to his brachial neuritis diagnosis, necessitating a reexamination of entitlement relative to that condition.

It is uncontroversial that brachial neuritis is, in general, an autoimmune condition associated with multiple triggers. (Ex. 21, p. 4 (citing Mark A. Ferrante & Asa J. Wilbourn, *Lesion Distribution Among 281 Patients with Sporadic Nerualgic Amyotrophy*, 55 MUSCLE & NERVE 858 (2017) (herein "Ferrante and Wilbourn") (Ex. 27).) Additionally, the parties agree that onset of petitioner's symptoms occurred within six days of his vaccination and therefore falls within the "medically appropriate timeframe for the onset of an immunological injury." (*See* ECF No. 74, p. 18; *see also* ECF No. 77 pp. 39-41.) Petitioner's treating physicians further concluded that petitioner's own medical history was indicative of *vaccine-caused* brachial neuritis based on the fact of petitioner's recent flu vaccination. (Ex. 7, pp. 17, 47, 53, 74, 78, 80, 85; Ex. 3, p. 6; Ex. 1, p. 2.)

Because the Court of Federal Claims has determined that petitioner has demonstrated that the flu vaccine can cause brachial neuritis as a matter of general causation (ECF No. 91, pp. 9-10), the treating physician opinions carry significant weight as to specific causation pursuant to *Althen* prong two. The Federal Circuit has recognized generally that "treating physicians are likely to be in the best position to

determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano v. Sec'y of Health & Human Servs.,* 440 F.3d 1317, 1326 (Fed. Cir. 2006) (quoting *Althen v. Sec'y of Health and Human Servs.,* 418 F.3d 1274, 1280 (Fed. Cir. 2005)). With diagnosis and general causation decided in petitioner's favor, there is no remaining reason on this record to doubt the treating physicians' opinions as to specific causation. Respondent has not asserted any other explanation for petitioner's condition and agrees that the post-vaccination timing is medically appropriate for an immunological injury.

There remains a disconnect within petitioner's supporting expert opinion by Dr. Napoli. On the one hand, his causal explanation was premised on his assumption that what petitioner suffered was a demyelinating injury. (Tr. 107-10 (Dr. Napoli testifying that he believes petitioner's brachial neuritis and radiculomyelitis are both demyelinating injuries and agreeing that his opinion is based on the idea that "causal evidence relating to one demyelinating condition is relevant in discussing other demyelinating conditions").) On the other hand, Dr. Napoli was ultimately persuasive in opining that petitioner's condition is best explained by the diagnosis of brachial neuritis. This diagnosis is strongly suggestive of an axonal injury. (Medlink, *supra*, at Ex. 23, p. 2 (petitioner's exhibit explaining that regarding brachial neuritis "available evidence suggests that an autoimmune pathogenesis, likely related to a genetic susceptibility most commonly generates an axon loss lesion (focal or multifocal) that involves predominantly motor axons"); *see also* Van Eijk, Groothuis & Van Alfen, *supra*, at Ex C, p. 5.)

Even in the absence of evidence definitively identifying the nature of petitioner's own nerve lesions (axonal versus demyelinating), this inconsistency potentially defeats the internal logic of Dr. Napoli's opinion if demyelinating and axonal nerve lesions point to different etiologies. However, the Court of Federal Claims has held that petitioner has shown that brachial neuritis can be caused by the flu vaccine via molecular mimicry irrespective of any distinction between axonal and demyelinating injuries. (ECF No. 91, p. 11.) In the context of that holding, it is not necessary to further probe this inconsistency in Dr. Napoli's opinion, because either type of lesion can be linked to the flu vaccine pursuant to petitioner's *Althen* prong one theory. Dr. Napoli's assessment of petitioner's brachial neuritis was otherwise reasonable and in agreement with the treating physicians' opinions.

The Court of Federal Claims has already held that petitioner satisfied his burden of proof under the first *Althen* prong with respect to the injury of brachial neuritis. In light of the Court of Federal Claims' holding, all of the above indicates that petitioner has also satisfied *Althen* prongs two and three by preponderant evidence. Further, respondent has not presented any factor unrelated to vaccination that would explain petitioner's condition. Accordingly, petitioner is entitled to compensation for his injury of brachial neuritis.

III. Conclusion

For all the reasons described above, I find that petitioner is entitled to compensation. Specifically, I find that petitioner has established by preponderant evidence that he suffered brachial neuritis caused-in-fact by his January 11, 2013 influenza vaccination. A separate damages order will be issued. Pursuant to Vaccine Rule 28.1(a), the clerk of court is directed to notify the assigned judge of the filing of this decision on remand.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master